RESEARCH PROPOSAL

Effectiveness of an Individualized Communication Protocol on Clinical Outcomes of Comatose Patients in selected Intensive Care Unit of Tertiary Care Hospital.

Submitted by

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BACKGROUND & RATIONALE OF THE STUDY

Effective communication is the base for all proficient nursing practice. The art &science of caring comprehensively for patients. Nurses are the professionals who have the maximal involvement withpatients[1]

The term 'conscious' or 'consciousness' derived from the Latin word 'conscious' meaning 'to know'. Altered state of consciousness include a span of conditions of a normal, paranormal or abnormal nature. The patient is unable to respond appropriately to what is going on around him.[1]

Altered Level of Consciousness (ALOC) is a state of full consciousness at the one end and coma on other hand. It is a result of various pathophysiologic disease, may be the result of any neurologic condition (Seizures ,Head injury, stroke) ,or due to overdose of any drug , intoxication of Alcohol),or any metabolic related disease like diabetic keto- acidosis , hepatic disease)1.

Every year 5 million deaths occurred in Intensive Care Unitsevery year according to the estimation of World Health Organization [WHO]. Approximately 3.2million of the patient get admitted in Critical Care units in India among them 80% patients are comatose among in which 48000 deaths are occurring every year.[2]

Communication is an activity of conveying meaningful information in the form of messages, symbols, thoughts, signs and opinion. Good communication competence and skill are very essential to assist individuals and their family member to prevent and to cope with the ICU experience of illness and suffering.[1]

Intensive Care Unit are setting where the critical patients are received and cared. Nurses often come in contact with comatose clients who get admitted to the critical care unit. These patients are sensorial deficit and have less mobility due to any trauma or any pathological state2

Verbal communication is easily avoided, When Nurses are caring unconscious or comatose patients and nurses thought that communication with comatose patient is unimportant and in consequential. Lack of proper and quality communication has serious

impact on physical and psychological health of the patient. In day to day life Nurses are dealing with patient who need respect and care which can be propagated by only effective communication.2

It is a fundamental right of every human being to know the things that has been done to him/her when he/she is in the stage of altered sensorium. Comatose patients appear to be completely unaware of their environment. Therefore it is impossible to determine whether they are aware of any stimulus in the immediate environment because these patient are not able to respond to any stimuli, many unconscious patients do remember what they heard during their stay in Intensive Care Units [3]. Hence, it is important for the nurses to concentrate on patient communication needs. Many patients recover their consciousness and shared their ICU experiences of what happened to them in their comatose phase. A patient said "I was unconscious as far as the medical staff were concerned, but I could hear. I knew I was on a ventilator. I could not move or do anything but I could hear".

Verbal communication is excellent mean for delivery of competence and skilled Nursing care Verbal and Non Verbal communication is a best way of orienting and providing significant sensorial source for comatose patient. Friendly interaction, providing necessary information and positive feedback would help the comatose patient to prevent any unpropitious psychological effects. Communication alone can prevent intensive medicine becoming apparatus medicine So Nurses must communicate as much as possible to all altered level of conscious patient so that they can receive optimum care and wellbeing. Nurses in the ICU can make distinctive contribution in their practice when they understand that the patient will preserve self-identity and self-esteem through proper communication.[4]

NEED FOR THE STUDY

Many patients in critical care units are unable to communicate verbally they can't express their personal individual thoughts, emotional state and unable to express their necessityto their career. When critically ill patient cannot respond to verbal commands sonurses underemphasize talking to them. Many Intensive care Unit nurses confess that communication is the aspect which could be easily missed in Intensive Care Units as it is a unidirectional communication process usually done by the Intensive nurse. Critical care nurses said that it was a demanding task which require great exertion or effort to converse with a patients when they are comatose and who are not responding to external Stimuli.1

Patient communication has long been recognized as a research priority in critical care, unfortunately, many of the studies in the area of communication with unconscious patients

suffer from design weaknesses, such as non-standardized practices, so definitive recommendations for clinical practice are difficult to make[5].However, there is no evidence that communication with unconscious patients causes any harm or serious physiological adverse events (PAE). In addition, recent developments in the field of functional neuro-imaging have resulted in dramatic evidence that unconscious patients can hear and seemingly retain some cognitive ability.[6]

Due to the lack of nurse and patient conversation consequences like high intensity of Mental Pressure and level of anxiety .therapeutic communication is a key for preservation,dignity & self-respect overall improve their well-being .Patient communication is a matter of greatest importance in Intensive care, Although several researches had been done to evaluate the clinical profits of coma arousal technique with unconscious patients, very few of them was conducted in India ,there is no clear evidence about the impact of communication technique on patient clinical outcomes of comatose patient.[7]

The Researcher during her clinical experience also observed that the nurses working in ICUs were following diverse practice on communication. It is a greater challenge for nurses who are taking care of comatose patient. To improve and provide better quality of care to comatose patients evidence based practice is the best way.

Evidence based Practice will help in boost up the prognosis among comatose patients, there is no written evidence based practice guidelines existing in our setting. Hence the Researcher felt the need for developing an Individualized Communication Protocol which willbring constancy in execution of nursing care.

RESEARCH STATEMENT

Effectiveness of an Individualized Communication Protocol on Clinical Outcomes of Comatose Patients in selected Intensive Care Unit of Tertiary Care Hospital.

Aim of the Study:

The aim of the present study is to develop and implement the Individualized Communication Protocol and to evaluate its effect on clinical outcomes of comatose patients admitted inintensive care unit.

Research questions:

Does Individualized communication protocol have any effect on clinical outcomes of comatose patients?

OBJECTIVES OF THE STUDY

PHASE-I

1. To develop Individualized Communication Protocol for staff nurses to be used for comatose patients.
2. To evaluate effectiveness of training on Individualized Communication Protocol on knowledge of staff nurses working in ICU.
3. To evaluate effectiveness of training on Individualized Communication Protocol on practice of the staff nurses working in ICU.
4. To find correlation of pre-test knowledge and practice of nurses working in ICU.
5. To find association between level of knowledge and socio-demographical variablesof nurses.
6. To find association between level of practice and socio-demographical variables ofnurses.
7. To assess opinion of nurses on Individualized Communication Protocol.

PHASE-II

8. To evaluate effectiveness of Individualized Communication Protocol implemented by nurses working in ICU on clinical outcomes of comatose patients in terms of physiological adverse events, level of consciousness, level of agitation and sedation and pain level.

OPERATIONAL DEFINITION:

Knowledge: it refers to the level of understanding of nurses working in ICU on communication with comatose patients as measured by structured knowledge questionnaire.

Practice: It refers to the skills manifested by nursing care actions on communication with comatose patients as measured by structured observational checklist.

Individualized Communication Protocol:- It refers to tailored communication approach implemented by ICU nurses with comatose patients, that involves components like environmental preparation before and during communication, use of verbal and non- verbal communication with comatose patients including orientation of self, to time, place and person , recovery status of the patient , explanation before carrying out nursing interventions , importance of patient in the family and about pleasant memories, use of verbal and non-verbal communication with patient's relatives/ attendants.

Effectiveness:- It refers to an effect of implementing an individualized communication protocol on clinical outcomes in comatose patients in terms of responsiveness, sedation, pain, and incidence of physiological adverse events.

Comatose patients: It refers to patients having Glasgow Coma Scale score ≤ 8/15 and admitted in Intensive Care Unit.

Clinical outcomes:-It refers to the clinical parameters of the comatose patients which reflect clinical condition of the patient such as:

Physiological adverse events: It refers to clinical parameters in terms of cardiovascular, respiratory, metabolic status of the comatose patient as measured by physiological clinical variable assessment tool.

Responsiveness: It refers to the level of consciousness of the comatose patient in terms eye response, motor response, brainstem reflex and Respiratory pattern as measured by Four Outline of Unresponsiveness scale.

Sedation level: It refers to the level of sedation of the comatose patient in term of combative to unrousable as measured by Richmond agitation sedation scale.

Pain level: It refers to the level of pain of the Comatose patient in terms of facial expression, upper limb movements and compliance with the Mechanical Ventilation as measured by behavioural pain scale.

REVIEW OF LITERATURE:

1. Study related to comatose patients and communication.
2. Study related to assessment of patient outcome.
3. Study related to verbal and non-verbal interventions for comatose patients.

1. **OthmanS.Y, Mohamed. M (2015)** conducted a quasi-experimental study to evaluate the efficacy of structured communication messages (SCMs) on patient clinical outcomes of unconscious patients. Total Sixty unconscious patients were randomly allocated into two groups (intervention and control group) 30 patients in each from three different ICUs The SCMs developed, had shown improvement in the communication with the unconscious patients so, it was recommended for Nurses to use for unconscious patients[8].
2. **Mohammed .M.H et.al (2017)** done a quasi-experimental study to evaluate the efficacy of coma arousal techniques on patient clinical outcomes parameters of unconscious patients. Total sixty patients were randomly allocated to (study& control group) 30 sample in each. Study show that control group had a significantly higher number of incidence rate of physiological parameters adverse events. Study concluded that implementation of coma arousal technique improves the level of consciousness and sensory and motor activities and reduce the incidence rate of physiological parameters adverse events[9].

3. **Moattari M[1], AlizadehShirazi F[1], Sharifi N[1], Zareh N[2].(2016)**Conducted a randomized clinical trial to assess that early sensory stimulation and regular family visiting programs are potential nursing interventions to improve the outcomes of head injured comatose patients. total 60 head injured comatose patients with an initial Glasgow coma score (GCS) of less than 8 were randomly assigned to receive sensory stimulation by a qualified nurse (nurse group; n = 20), by the family (family group; n = 20), or usual care (control group; n = 20). The sensory stimulation program involving the nurses and patients' families was conducted, twice daily, in the morning and evening for 7 days. The level of consciousness, level of cognitive function, and basic cognitive sensory recovery of the patients were evaluated and monitored .Although the two intervention groups of the study improved, those who received the sensory stimulation program from their families had significantly higher GCS (P = 0.001), RLA (P = 0.001), and WNSSP (P = 0.001) scores after 7 days when compared to the two other groups. The application of sensory stimulation by families led to significant increases in the consciousness, level of cognitive function, and basic cognitive sensory recovery of comatose patients with severe injuries[10].

HYPOTHESES:

H1 There would be significant improvement in knowledge of nurses after receivingtraining program on Individualized Communication Protocol

H2 There would be significant improvement in practice of nurses after receivingtraining program on Individualized Communication Protocol.

H3 Comatose patients in experimental group would have significantly lowerincidence of Physiological adverse event as compared to control group.

H4 Comatose patients in experimental group would have significant improvementin consciousness compared to Control group.

H5 Comatose patients in experimental group would have lower sedation score ascompared to control group.

H6 Comatose patients in experimental group would have significant lesser painlevel as compared to control group.

ASSUMPTION

The study assumes that:-

1. The sample will be the true representation of the population.
2. Staff nurses working in the ICU face obstacles to communicate with comatose patients while caring.
3. Staff nurses will give honest responses.

DELIMITATIONS

This study is delimited to:

1. Self -developed knowledge and practice checklist.
2. Number of the study participants
3. Time of data collection (morning and evening shift).
4. Follow up will be limited to a duration of 2 weeks only.

RESEARCH METHODOLOGY:

Research Approach: Quantitative Research Approach.

Research design: A Quasi experimental Study Design will be used in carrying out the study.

Population-Comatose patients with GCS≤8/15admitted in ICU of tertiary care hospital
Setting -This study will be conducted in intensive care unit of tertiary care hospital.
Sample- Comatose Patient with GCS≤8/15 admitted in ICU of tertiary care hospital during data collection period and meet the inclusion criteria.
Sampling Technique:

Sampling Technique: - Purposive Sampling technique first 45 in control and next 45 willbe in experimental group.

Sample size- Total 90 comatose Patient will be assigned to control (45patients) and Experimental Group 45 Patients).

$$\textbf{Effect Size} = \frac{\textbf{[Mean of experimental group]} - \textbf{[Mean of control group]}}{\textbf{Standard Deviation}}$$

Inclusion Criteria:

The sample will consist of patients who:

1. Have age between 18 to 65 years
2. Are on Mechanical Ventilation.
3. Presents with GCS score≤8/15

Exclusion Criteria: All Patient were excluded from the study who:

1. Had history of impaired hearing.
2. Were diagnosed Injury of the Auditory pathways.
3. Were induced Coma by infusion of Neuromuscular Blockade.

Inclusion Criteria for Nurses:

- Nurses who are available at the time of data collection.
- Nurses who are willing to participate in the study

Variables:

Independent variables: Individualized communication protocol.

Dependent Variable: Knowledge and practices of nurses regarding Individualized communication protocol.

Dependent variables: Clinical outcomes of the comatose patients in terms of physiological clinical variables, responsiveness, sedation and pain.

Socio-demographic variable:

- Age
- Gender:
- Marital status
- Level of Education
- Place of Living
- Occupation

Clinical Variables

- Medical Diagnosis:
- Admission to ICU from Ward/ Emergency.
- Level of Consciousness (LOC) (GCS- Score) on Admission to ICU
- On Mechanical Ventilation (MV) ----Yes/No
- ICU length of stay

- APACHE II Score at the time of Admission

DESCRIPTION OF TOOLS

Five tools will be used for data collection in this study.

Tool I: Structured questionnaire for demographic and clinical profile

This tool is composed of two parts:

*Part One:*It deals with demographic variables of the patient's like age, gender, marital status, level of education, place of living, occupation .

*Part two:*Clinical variables like medical diagnosis ,admission to ICU, level of consciousness (LOC) in the beginning of the study, ICU length of stay(ICU LOS) and duration of mechanical ventilation(MV), APACHE II score .

Tool II: It deals with physiological adverse event assessment tool contain parameters including "temperature(T),systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), oxygen saturation (SpO_2), respiratory rate (RR)and blood glucose level (BGL)".The PCV parameters will be organized in a flow sheet to document patient's data from the beginning to the end of the study. These parameters will be defined as appearance of clinically relevant changes after communication including the followings:

- Tachycardia: heart rate ≥ 100 beats/minute(b/min)
- Bradycardia: heart rate ≤ 60b/min
- Hypertension: SBP ≥140 mmHg, DBP ≥90 mmHg
- Hypotension:SBP≤95mmHg,DBP≤60mmHg
- Hyperthermia: T ≥37.5˚C
- Desaturation: oxygen saturation ≤90%
- Bradypnea: respiratory rate ≤ 12cycle/min
- Ventilatory distress: severe ventilator asynchrony(non- stop coughing or impossible ventilation) and/or tachypnea (respiratory rate ≥ 35cycle/min).
- Hyperglycemia: blood glucose level (BGL) ≥ 200 mg/dl
- Hypoglycemia: BGL < 70mg/dl.

- **Tool III: Full Outline of Un-Responsiveness (FOUR) scale –**

This scale is adopted from Wijdicks [11] to assess patient's level of consciousness after conducting communication practices. It has 4 components: eye responses, motor responses, brainstem reflexes, and respiration pattern (including mechanical ventilation).The maximum score for the four items is 4.The total score ranges from 0 to16.A score of 0 on the FOUR scale assumes the absence of brainstem reflexes and breathing while, 16 indicates full consciousness.

- **Tool IV The Richmond Agitation–Sedation Scale (RASS)**

This scale is adopted to assess the patient's level of agitation and sedation .RASS is a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative]), one level to denote a calm and alert state (0), and 5 levels of sedation (−1 to −5) culminating in unarousable (−5). The values and definitions for each level of agitation and sedation are displayed [12].

- **Tool V: Behavioural Pain Scale (BPS)**

This scale is adopted from Payen *et al.*[13]to assess patient's comfort/pain level after performing communication practices. It is based on the sum score of three behavioural expressions: facial expressions (relaxed, partially tight, fully tightened, or grimacing), upper limb movements (nomovement, partially bent, fully bent with finger flexion, or permanently retracted) and compliance with mechanical ventilation (tolerating movement, coughing with movement, fighting ventilator, or unable to control ventilation). Each item of the three behavioural expressions is scored from 1to4,with higher numbers indicating higher levels of discomfort. The total BPS score can range from 3(no pain) to12 (most pain).

<u>Tool for assessment of knowledge and Practice of the nurses working in ICUs</u>

Tool No -6: Structured questionnaire for Personal profile.

It is a self-structured tool and contains 24 items. It is divided into two sections:

Section- A: Personal Profile

The investigator worked on literature, also consulted with field of experts to study the different type of variables which will influence the outcome of study. Considering literature and field of expert's suggestions the following variables included in the personal Profile i.e age, gender, marital status. Professional Qualification area of experience, Year of experience in clinicals, additional -qualification and nurse patient ratio.

Section- B: Structured Knowledge Questionnaire

The investigator reviewed both research and non-research literature to prepare the content on communication for patients with comatose patients . The guidance was taken from experts and a blue print was prepared specifying the content areas and domains.

The questionnaire consisted of 24 multiple –choice items. The Minimum and Maximum score was 0 -24. The correct answer scores 1mark and wrong answer scores 0 (zero) . The investigator assumes that the score above 15 will be considered as Average score.

INTERPRETATION:

Minimum score – 0 Maximum score – 24 If score is:

0 – 8 = Good Knowledge

9- 15 =Average

16 – 24 = Below Average

Section-C: Structured Observational check list

The investigator reviewed the textbooks, journals, Short communications, Internet, opinion and suggestions from the experts, also patient views were considered to formulate an Observational checklist on communication with comatose patients

The observational checklist consists of the Following domains:

a) Environmental preparation

b) Verbal communication with comatose patients

c) Non-verbal communication with comatose patients

d) Family verbal communication

The Minimum and Maximum score was 1-43. Every successful communication event carry 1 mark and unsuccessful event carry 0 mark. The investigator assumes that the score above 15 will be considered as average score.

SCORE INTERPRETATION

Good- 28 and above communication Skills

Average -15- 28 average communication Skills

Below Average- 0-14 Below average communication Skills.

Section-D: Structured opinionnaire for nurses working in ICUs

It consisted of eight items on acceptability of individualized communication protocol by nurses working in ICUs and All items had alternative columns to mark the opinion by putting a tick with options of "accept fully,' accept ,do not accept. "agree," and "disagree."

VALIDITY & RELIABILITY OF TOOLS

a) Reliability of Four Outline of unresponsiveness Scale Cranach α 0.87 and a Kappa coefficient - 0.99).

b) Reliability and Validity of Richmond Agitation Sedation Score r=0.95 kappa coficient-0.71.

c) Reliability of the Behavioral Pain Scale Kappa coefficient of 0.94 was assessed by Payenet al.

d) Content validity of the structured Tools

The validity is the degree to which an instrument measures what it is intended to measure. For ensuring the content observational and knowledge questionnaire and opinionnaire will given to nine field experts and they were requested to give opinion about the coverage of content areas, relevancy, clarity and appropriateness. Among the nine experts, five were from the field of nursing and four were from the department of Critical care medicine .

PLAN OF DATA COLLECTION

Preparation of Intervention: Individualized communication Protocol include four components:

Environmental preparation:

An extensive literature review was conducted by the researchers to identify all available evidences concerning environmental preparation which include: providing privacy, maintaining personal space during care, Maintain environment feasible for effective communication, Create a safe comfortable environment, Communicate according to stages of development etc.

Formulation of verbal messages

An extensive literature review was conducted by the researchers to identify all available evidences concerning verbal communication with comatose patients. The content of verbal messages was based on the results reported in the literature,

The standardized criteria for verbal communication to comatose patients are identified such as: using the appropriate voice tone, not speaking too loud or shouting, avoiding parallel talk while care procedures are performed, communicating with the patient directly, simplifying language by using short and uncomplicated sentences, repeating the content words or key words to clarify meaning as needed, maintaining a natural conversational manner appropriate for an adult, minimizing distractions.

The construction of a message which should include both pleasant contents(*e.g.*Your family told me they really like you and that they wish you recover quickly) and orders (*e.g.*, Mr./Mrs. A, I'm here to help you, come on, open your eyes).

Formulation of verbal messages contents comprise of introducing the speaker and orientating patient , calling the patient by his name, greeting the patient, identifying the health professional or relative (name, profession or relationship),stating the date, day of the week and the weather, and explaining their current location. Finally, explaining the procedure before performing it and reassuring the patient at the end of each procedure; explaining patient's progress, and communicating the present condition of the patient, providing the patient within formation about: current affairs; saying something about their family life and somesentences about recovery and coming back to family in the future; sweet memories, and telling a message of affection and with an optimistic perspective.

Formulation of non-verbal messages

The content of structured non-verbal communication was based on the results reported in the literature. It included therapeutic touch, facial expressions, posturing and eye contact. The three types of therapeutic touch were included: caring touch (gives comfort and reassurance to the patient) ;task touch which is concerned with performing nursing procedures ;and protective touch which is concerned with protecting the patient from accidents.

Study will be conducted in 2 phase :

Phase –I-Knowledge and practice of the Nurses regarding communication will be assessed by Knowledge questionnaire and practice checklist respectively.

Phase-II- During this phase the clinical outcomes of both groups (control and intervention) will be evaluated. The PCV (hyperthermia, hypothermia, tachycardia, bradycardia, hyper-

tension, hypotension, desaturation, bradypnea, ventilator distress, hyper glycemia or hypoglycemia), FOUR score, BPS score, and RASS score will be considered as primary outcomes.

Phase Two: Part 1

- During this phase, the researcher will be observing the clinical outcomes for patients in the control group who received the routine communication practices provided by nurses in the ICUs. Patients in this group will be followed up by the researchers after 24 hours of ICU admission until ICU discharge.
- Data will be collected by assessing clinical outcomes after nursing communication practices that will be performed during the routine daily care (complete bed bath, tracheal tube suction, physiotherapy) which were performed in the morning (8-9 Am) and at the end of evening shift (7-8Pm).

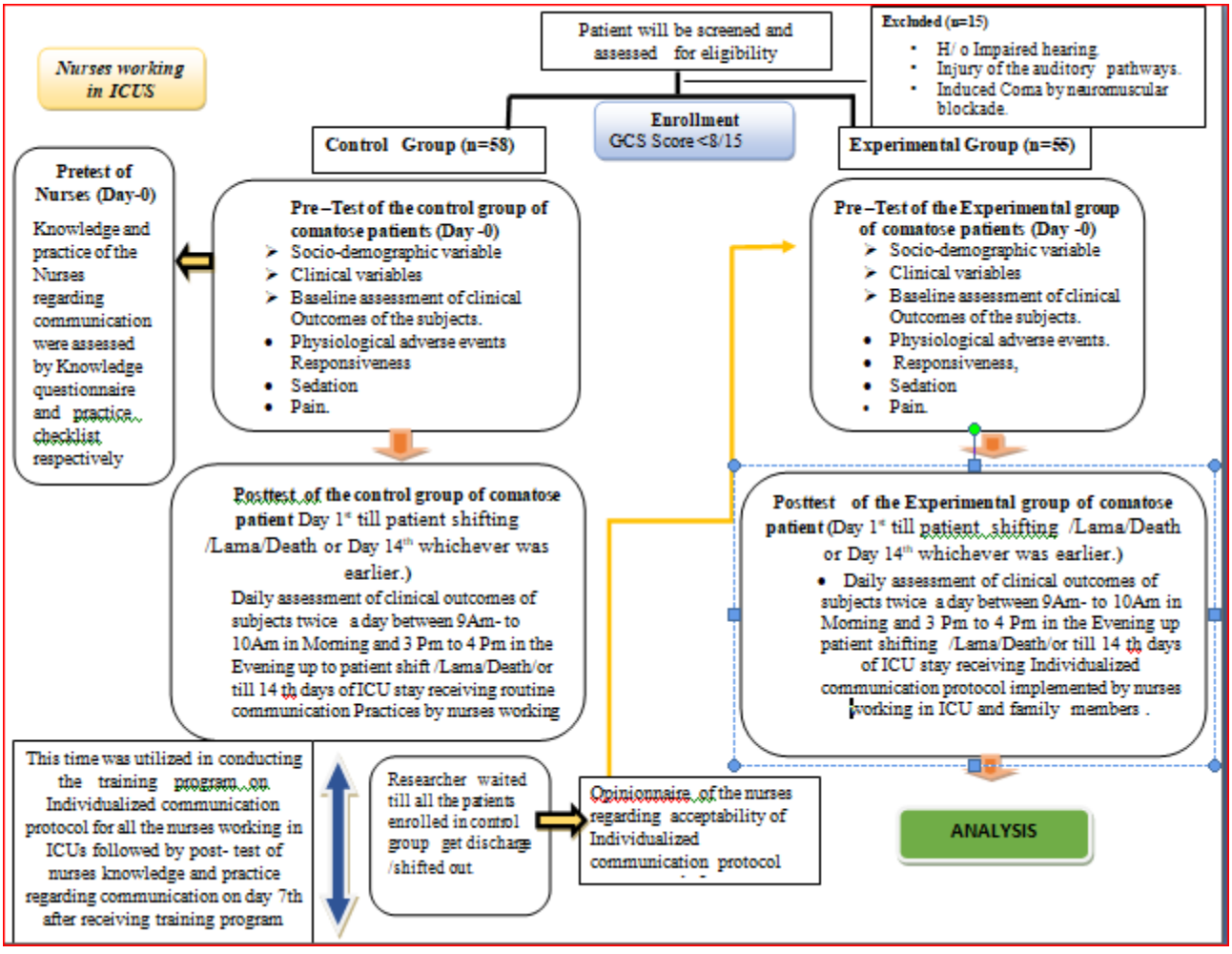
  Patients' parameters including (T, HR,SBP, DBP, SpO_2, RR, and BGL) will be assessed and recorded (tool I part two)twice daily (8-9Am and7-8 Pm) until ICU discharge. The appearance of any PAE (hyperthermia, hypothermia, tachycardia, bradycardia, hypertension, hypotension, desaturation, bradypnea, ventilatory distress, hyperglycemia or hypoglycemia) was recorded on the same tool. The incidence of PAE is defined by the proportion of patients who developed at least one PAE while being communicated.
- Patient's LOC will be assessed by FOUR scale twice daily (8-9 Am and 7-8 Pm) until ICU discharge using Tool II.
- Patient's pain/comfort level will be assessed by BPS twice daily (8-9 Am and 7-8 Pm) until ICU discharge using Tool III.
- Patient's sedation or restlessness level will be assessed by RASS twice daily (8-9 Am and 7-8 Pm) until ICU discharge using Tool IV.

Phase II- Part: 2

- During this phase the nurses and patient's closest relative of the intervention group will be interviewed to determine the patient's social history and personality characteristics. After 24 hours of patient's admission to the intended ICUs, the researcher will review patient's chart to document socio-demographic and health relevant data using part one of tool I.
- Verbal communication practices will be performed during each procedure by the nurses when they contacted patient.
- Nonverbal communication practices will be performed in combination with verbal practices.
- The family members will be encouraged to communicate "verbally and non-verbally" with their patients during visiting hours.

- Patients in the intervention group will be followed up by the researcher after 24 hours of ICU admission till 14 days. Patients' PAE parameters including (T, HR, SBP, DBP, CVP, SpO2, RR, and BGL) will be assessed and recorded (tool I part two) twice daily (8-9 Am and 7-8 Pm) until ICU discharge. The appearance of any of PAE (hyperthermia, hypothermia, tachycardia, bradycardia, hypertension, hypotension, hypovolemia, hypervolemia, desaturation, bradypnea, ventilatory distress, hyperglycemia or hypoglycemia) will be recorded on the same tool. Patient's LOC will be also evaluated by the FOUR scale twice daily till 14days. Then patient's pain/comfort level will be assessed by BPS twice/day till 14 days. Patient's sedation or restlessness level will be assessed by RASS twice daily till 14 days.

Plan of data collection


Nurses working in ICUS
Patient will be screened and assessed for eligibility
Excluded (n=15)
H/ o Impaired hearing.
Injury of the auditory pathways.
Induced Coma by neuromuscular blockade.
Enrollment
GCS Score <8/15
Control Group (n=58)
Experimental Group (n=55)
Pretest of Nurses (Day-0)
Knowledge and practice of the Nurses regarding communication were assessed by Knowledge questionnaire and practice checklist respectively
Pre –Test of the control group of comatose patients (Day -0)
Socio-demographic variable
Clinical variables
Baseline assessment of clinical Outcomes of the subjects.
Physiological adverse events Responsiveness
Sedation
Pain.
Pre –Test of the Experimental group of comatose patients (Day -0)
Socio-demographic variable
Clinical variables
Baseline assessment of clinical Outcomes of the subjects.
Physiological adverse events.
Responsiveness,
Sedation
Pain.
Posttest of the control group of comatose patient Day 1st till patient shifting /Lama/Death or Day 14th whichever was earlier.)
Daily assessment of clinical outcomes of subjects twice a day between 9Am- to 10Am in Morning and 3 Pm to 4 Pm in the Evening up to patient shift /Lama/Death/or till 14 th days of ICU stay receiving routine communication Practices by nurses working
Posttest of the Experimental group of comatose patient (Day 1st till patient shifting /Lama/Death or Day 14th whichever was earlier.)
Daily assessment of clinical outcomes of subjects twice a day between 9Am- to 10Am in Morning and 3 Pm to 4 Pm in the Evening up patient shifting /Lama/Death/or till 14 th days of ICU stay receiving Individualized communication protocol implemented by nurses working in ICU and family members .
This time was utilized in conducting the training program on Individualized communication protocol for all the nurses working in ICUs followed by post- test of nurses knowledge and practice regarding communication on day 7th after receiving training program
Researcher waited till all the patients enrolled in control group get discharge /shifted out
Opinionnaire of the nurses regarding acceptability of Individualized communication protocol
ANALYSIS

- **PILOT STUDY:**

A pilot study will be done after the development of the tools and before starting data collection on 10% of the study sample (4 patients) who will be excluded from the total sample. The aim of the pilot study will be determine the clarity, feasibility, applicability and determine the required time to fulfill the designed tools. Then accordingly necessary modifications will be done.

Administrative Permission will be taken from the Dean Research, Medical Superintendent, Nursing Superintendent, and Hospital Authorities in the Intensive Care Units.

ETHICAL CONSIDERATION:

1. Ethical Clearance has been obtained from Ethical Committee SRHU.
2. Written informed consent will be obtained from the Critical Care Nurses to participate in the study
3. Written informed consent will be obtained from the patients' family to participate in the study after explaining the purpose of the study and their right to refuse participation or withdrawn from the study at any time.
4. Patients' attendants/relatives will be assured that if they did not want to participate in the study, this will have no effect on the quality of care received by them in ICU.

DATA MANAGEMENT & ANALYSIS:

Data Analysis will be based on objectives and Hypotheses stated in the study using Descriptive and Inferential Statistics.

- All data will be coded and then entered in the master data sheet.
- Analysis of the data will be done by using descriptive and inferential statistics. The socio-demographic and clinical variables will be described using frequencies, percentage, mean, and standard deviation.
- Categorical variables will be compared using Chi square test and Fischer's exact test as applicable.
- The two groups will be compared with Student t test (parametric data) and Mann–whitney test (nonparametric data)
- Pearson correlation will be used to find out the correlation between socio-demographic, clinical variables.

SUMMARY OF INDIVIDUALIZED COMMUNICATION NURSING CARE OBSERVATION

Event	Nursing Care Task	MORNING	EVENING
1	Hygenic care		
2	Feeding		
3	Suctioning		
4	Positioning		
5	Family Visit		

NURSING IMPLICATION

Incorporating communication in the nursing standards will ensure that patients are treatedwith dignity which will help in improve patient outcomes. It will holistically improve the quality care which joins patient mind to its coma state and patient body to its vegetative state.

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